



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---------------|----------------------|---------------------|------------------|
| 10/765,943 | 01/29/2004 | Yasuyuki Numajiri | 00862.023438. | 1830 |
| 5514 | 7590 | 08/13/2008 | EXAMINER | |
| FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112 | | | SHAW, AMANDA MARIE | |
| ART UNIT | PAPER NUMBER | | | |
| | 1634 | | | |
| MAIL DATE | DELIVERY MODE | | | |
| 08/13/2008 | PAPER | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/765,943 | NUMAJIRI, YASUYUKI | |
| | Examiner | Art Unit | |
| | AMANDA SHAW | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 May 2008.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 28-33 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 28-33 is/are rejected.
 7) Claim(s) 28 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 29 January 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>5/29/2008, 8/4/2008</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 27, 2008 has been entered.

Claims 28-33 are currently pending. Claims 28-33 are also newly presented.

Withdrawn Rejections

2. All of the rejections made in the Office Action of February 27, 2008 are moot in view of the cancellation of claims 6-9, 15, 17-19, and 25-27.

Claim Objections

3. Claim 28 is objected to because of the following informalities: the phrase “used to check health condition” should be “used to check a health condition”. Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 32-33 are drawn to testing method using a DNA microarray. The method comprises a reading step, a acquisition step, a comparison step, and a generation step. The methods as claimed, do not produce any physical transformation or produce a tangible result. The claims as written do not appear to require any actual manipulations or active method steps, but rather encompass mere mental steps i.e. reading a preexisting hybridization pattern.

The courts have stated that "While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be."; Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759 ("steps of locating' a medial axis, and creating' a bubble hierarchy... describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic abstract idea") (see MPEM § 2106 IV).

The courts have stated that manipulation of abstract concepts or ideas constitute non-statutory subject matter.

If the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 USPQ2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of

numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they: consist solely of mathematical operations without some claimed practical application (i.e., executing a "mathematical algorithm"); or simply manipulate abstract ideas, e.g. a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application. (see MPEP § 2106 IV (g)(1)).

It is further noted that In re Schrader states: "the grouping or regrouping of bids cannot constitute a physical change, effect or result".... "The only physical effect or result which is required by the claim is the entering of bids in a "record," a step that can be accomplished simply by writing the bids on a piece of paper or chalkboard. For purposes of Section 101, such activity is indistinguishable from the data gathering steps which we said in In re Grams, 888 F.2d 835, 12 USPQ 2d 1924 (Fed. Cir. 1989), were insufficient to impart patentability to a claimed involving the solving of a mathematical algorithm". Therefore, the courts have stated that identifying without physical manipulation, is indistinguishable from data gathering and insufficient to impart patentability. Since the instant claims do not require any type of wet step i.e., hybridizing DNA to the array, the claims are considered to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 112 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is indefinite over the recitation of the phrase "when the identification information acquired in the acquisition step is not stored in the storing means, determines that the particular subject is a new subject and stores the test information in association with the acquired identification information". This phrase is considered indefinite because it is unclear whether or not the identification information is being stored.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hogan (US 2002/0110823 Pub 8/2002).

Regarding Claim 30 Hogan teaches a method wherein a sample from a perioperative subject is used to generate a genomic profile for that subject. Hogan teaches that in some embodiments the genomic profile includes a set of markers that provide information that can be used to determine the course of treatment (Para 0126). Hogan further teaches that in some embodiments the genomic profile includes a set of unique genomic identifiers (e.g., a series of polymorphic non coding SNPs) used to determine the identity of the subject (Para 0134). Additionally Hogan teaches that in preferred embodiments the genomic profiles are generated by hybridizing a nucleic acid sample to a DNA microarray and detecting hybridization (Para 0167-0176). Thus Hogan teaches a method that comprises hybridizing a DNA sample to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject (Para 0167-0176). Hogan teaches that after the sequence information has been generated the information can be stored (e.g., as digital information on a portable chip) (para 0186). Thus Hogan teaches a method further comprising storing test information into storing means.

8. Claims 28-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Hashmi (US 2004/0048259 Filed 9/2002).

Hashmi teaches a method for genetic testing of an organism and for correlating the results of the genetic testing with a unique marker (i.e. SNP profile) that unambiguously identifies the organism (Abstract). Hashmi teaches that patients sample is contacted with a first set of probes that is used in an assay designed for genetic testing and the second set of probes is used in the determination of a molecular fingerprint (para 0089). Thus Hashmi teaches a method that comprises hybridizing a DNA sample to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject. Hashmi further teaches that after the sequence information has been generated the information can be stored in a database (para 0131). Thus Hashmi teaches a method further comprising storing test information into storing means. Hashmi also teaches that if subsequent testing is performed the results of the second test may be verified unambiguously by comparing the genetic fingerprints associated with the first and second tests. Thus Hashmi teaches comparing first and second identification information.

9. Claims 30-31 rejected under 35 U.S.C. 102(e) as being anticipated by Barrett (US 2005/0064436 Filed 9/2003).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Barrett teaches a method wherein a SNP profile is determined for a nucleic acid sample, where the determined SNP profiled is then employed to identify the source of the sample, e.g., the subject or patient from which the sample was obtained. Barrett further teaches that the sample can also screen for a condition, e.g., a disease. In some embodiments the sample is screened for a SNP profile and a disease simultaneously using an array of probes wherein the array includes both SNP probe features and disease probe features (para 0063). Thus Hogan teaches a method that comprises hybridizing a DNA sample to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject. Barrett further teaches that after the sequence information has been generated the information can be stored (e.g., as digital information in a database) (para 0053-0055). Thus Barrett teaches a method further comprising storing test information into storing means.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 28-29 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (US 2002/0110823 Pub 8/2002 Filed 10/2001) in view of Beecham (US Patent 5876926 Issued 1999).

Hogan teaches a method wherein a sample from a perioperative subject is used to generate a genomic profile for that subject. Hogan teaches that in some embodiments the genomic profile includes a set of markers that provide information that can be used to determine the course of treatment (Para 0126). Hogan further teaches that in some embodiments the genomic profile includes a set of unique genomic identifiers (e.g., a series of polymorphic non coding SNPs) used to determine the identity of the subject (Para 0134). Additionally Hogan teaches that in preferred embodiments the genomic profiles are generated by hybridizing a nucleic acid sample to a DNA microarray and detecting hybridization (Para 0167-0176). Thus Hogan teaches a method that comprises hybridizing a DNA sample to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject (Para 0167-0176). Hogan teaches that after the

sequence information has been generated the information can be stored (e.g., as digital information on a portable chip) (para 0186). Thus Hogan teaches a method further comprising storing test information into storing means.

Hogan does not teach a method comprising acquiring information recorded on a medical card owned by the subject and comparing the identification information on the microarray to the identification information on the medical card.

However Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data of Beecham is being interpreted as the second probe hybridization pattern and the stored biometric data of Beecham is being interpreted as the medical card. Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hogan by comparing the identification information on the microarray to the identification information on the medical card before recording the patients test results on the medical card as suggested by Beecham. One of skill in the art would have been motivated to make the comparison in order to prevent someone from obtaining someone else's private medical information.

12. Claims 28-29 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrett (US 2005/0064436 Filed 3/2005) in view of Beecham (US Patent 5876926 Issued 1999).

Barrett teaches a method wherein a SNP profile is determined for a nucleic acid sample, where the determined SNP profile is then employed to identify the source of the sample, e.g., the subject or patient from which the sample was obtained. Barrett further teaches that the sample can also screen for a condition, e.g., a disease. In some embodiments the sample is screened for a SNP profile and a disease simultaneously using an array of probes wherein the array includes both SNP probe features and disease probe features (para 0063). Thus Hogan teaches a method that comprises hybridizing a DNA sample to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject. Barrett further teaches that after the sequence information has been generated the information can be stored (e.g., as digital information in a database) (para 0053-0055). Thus Barrett teaches a method further comprising storing test information into storing means.

Barrett does not teach a method comprising acquiring information recorded on a medical card owned by the subject and comparing the identification information on the microarray to the identification information on the medical card.

However Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data of Beecham is being interpreted as the second probe hybridization pattern and the stored biometric data of Beecham is being interpreted as the medical card. Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Barrett by comparing the identification information on the microarray to the identification information on the medical card before recording the patients test results on the medical card as suggested by Beecham. One of skill in the art would have been motivated to make the comparison in order to prevent someone from obtaining someone else's private medical information.

Response To Arguments

13. In the response filed May 27, 2008, the Applicants respectfully submit that the new claims are patentable over the previously cited art. The amendments have been fully considered and the Examiner has provided new art rejections based on the claims as amended.

Regarding Claim 32 the Applicants state that in the claims the test is not performed when a subject is not identified which can enhance privacy protection of the subject. However it is noted for the record that the claims are not limited to this.

Further Regarding Claim 33 the Applicants state that even the reading of the hybridization pattern of the second DNA probe group is not performed when the subject in not identified. Again the claims are not actually limited to this.

Conclusion

14. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1634

Amanda M. Shaw
Examiner
Art Unit 1634

/Carla Myers/
Primary Examiner, Art Unit 1634